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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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09/346,923 07/02/99 DAWSON

C 03543-0250-U

EXAMINER

022930 HM12/0919

HOWREY SIMON ARNOLD & WHITE LLP

BOX 34

1299 PENNSYLVANIA AVENUE NW

WASHINGTON DC 20004

FEEL EV: 6

PAPER NUMBER

1623

DATE MAILED:

09/19/00

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 8/11/00

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-29 and 36-45 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-29 and 36-45 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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Claims 36-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/09601 for the reasons set forth in the Office Action of April 14, 2000.

Applicant's arguments filed August 11, 2000 have been fully considered but they are not persuasive.

Claims 1-29 and 36-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Dawson (First Meeting of the WHO alliance for the Global elimination of Trachoma, Geneva, 30 June-1 July 1997) for the reasons set forth in the Office Action of April 14, 2000.

Applicant's arguments filed August 11, 2000 have been fully considered but they are not persuasive.

Applicants have not presented any evidence showing that the Dawson paper was not publicly available before the priority date of the present application.

Applicants further argue that the disclosure by Dawson is not enabling. This argument has not been found persuasive. Note that claim 1 reads on topically applying an azalide antibiotic to the eye in order to treat or prevent infection in a tissue of an eye. Dawson teaches on page 2 that "there are now several vehicles that are administered as a drop and persist in the eye, releasing drug over a long period of time (Table 1). The advantage of such a preparation is that the azithromycin would be in contact with the conjunctiva for a prolonged period of time".

Claims 1-29 and 36-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over the First Meeting of the WHO alliance for the Global Elimination of Trachoma, Geneva, 30 June-1

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July 1997 in combination with WO 95/09601 for the reasons set forth in the Office Action of April 14, 2000.

Claims 1-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what is encompassed by the term "prevent" (claim 1) i.e. it is not clear whether prevention is achieved for a period of days, months, years or whether permanent prevention is achieved.

Applicant's arguments filed August 11, 2000 have been fully considered but they are not persuasive.

The term "prevent" reads on applying claimed composition to the healthy eye and permanently preventing infection from occurring. However, the specification does not disclose the treatment of healthy subjects.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peshev whose telephone number is (703) 308-4616. The examiner can normally be reached on weekdays from 9.30 a.m. to 6.00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

*elli peshev*  
ELLI PESELEV  
PRIMARY EXAMINER  
GROUP 1200